



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,441	11/28/2000	Paul D. Hanke	1533.1030002/SRL/SEZ	4696

7590

03/20/2002

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Attorneys at Law

Suite 600

1100 New York Avenue, N.W.

Washington, DC 20005-3934

EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/20/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/722,441

Applicant(s)

HANKE ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Application Status***

1. Claims 1-67 are pending in the instant application.

### ***Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claim 1, drawn to aspartokinase polypeptides, classified in class 435, subclass 194.
  - II. Claims 2-29 and 61-67, drawn to polynucleotides, vectors, host cells, and methods related to SEQ ID NO:1, classified in class 435, subclass 15.
  - III. Claims 30-44, drawn to methods of making lysine, classified in class 435, subclass 115.
  - IV. Claims 45-46, drawn to polypeptides related to SEQ ID NO:19, classified in class 530, subclass 350.
  - V. Claims 47-52, drawn to polynucleotides, vectors, host cells, and methods related to SEQ ID NO:19, classified in class 435, subclass 15.
  - VI. Claims 53-54, drawn to polypeptides related to SEQ ID NO:21, classified in class 530, subclass 350.
  - VII. Claims 55-60, drawn to polynucleotides, vectors, host cells, and methods related to SEQ ID NO:21, classified in class 435, subclass 15.

Art Unit: 1652

3. The inventions are distinct, each from the other because of the following reasons:

The DNA of Group II is related to the enzymes of Group I by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups I and II are patentably distinct.

Groups I and III are related because the DNA that encodes the proteins of Group I is used in the host cells that are used in the methods of Group III. However, the isolated polypeptides of Group I are not used in the methods of Group III. Thus, Groups I and III are patentably distinct.

Groups I, IV, and VI are related as polypeptides having the same basic structure of linear amino acids. However, each of these Groups is defined in the specification according to distinct sequences. These distinct sequences foster distinct three dimensional protein structures that facilitate distinct functions in each of the proteins. Thus, Groups I, IV, and VI are patentably distinct, each from the other.

Groups I and II are unrelated to Groups V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions, that is the proteins of Group I and the encoding DNAs of Group II function

Art Unit: 1652

as distinct proteins in distinct host cells from those used in the methods of Groups V and VII.

Thus, Groups I and II are each patentably distinct from Groups V and VII.

Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of Group II can be used for a materially different process of using that product, such as in hybridization assays to identify similar DNA sequences. Thus, Groups II and III are patentably distinct.

Group II is unrelated to Groups IV and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions, that is the DNA of Group II function to encode distinct proteins in distinct host cells from the proteins of Groups IV and VI. Thus, Group II is patentably distinct from Groups IV and VI.

Group III is unrelated to Groups IV-VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions, that is the methods of Group III do not utilize the products of or the method steps of Groups IV-VII. Thus, Group III is patentably distinct from Groups IV-VII.

Art Unit: 1652

The DNA of Group V is related to the enzymes of Group IV by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups IV and V are patentably distinct.

Groups IV and V are unrelated to Groups VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions, that is the proteins of Group IV and the encoding DNAs of Group V function as distinct proteins in distinct host cells from the proteins of Group VI and the encoding DNAs of Group VII. Thus, Groups IV and V are each patentably distinct from Groups VI and VII.

The DNA of Group VII is related to the enzymes of Group VI by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups VI and VII are patentably distinct.

Art Unit: 1652

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Distinct class/subclass classifications present a search burden on the Examiner if examined together, such between Groups I, II, and III. Moreover, Groups IV and VI, while identically classified, would present a search burden if examined together due to the distinct sequence searches that would not be co-extensive. Also, Groups III, V, and VII, while identically classified, would present a search burden if examined together due to the distinct sequence searches that would not be co-extensive

#### ***Restriction of Species***

5. This application contains claims directed to the following patentably distinct species of the claimed invention. In Group II, species of DNA, vectors, and methods containing DNA encoding SEQ ID NO:2 are:

- a) DNA encoding SEQ ID NO:2 AND an *asd* gene (Claims 8-10, 16-17, and 25-29)
- b) DNA encoding SEQ ID NO:2 AND an *dapA* gene (Claims 8-10, 16-17, and 25-29)
- c) DNA encoding SEQ ID NO:2 AND an *dapB* gene (Claims 8-10, 16-17, and 25-29)
- d) DNA encoding SEQ ID NO:2 AND an *ddh* gene (Claims 8-10, 16-17, and 25-29)
- e) DNA encoding SEQ ID NO:2 AND an *lysA* gene (Claims 8-10, 16-17, and 25-29)
- f) DNA encoding SEQ ID NO:2 AND an *lysA* gene (Claims 8-10, 16-17, and 25-29)
- g) DNA encoding SEQ ID NO:2 AND an *ORF2* gene (Claims 8-10, 16-17, and 25-29)
- h) DNA encoding SEQ ID NO:2, *asd*, *dapA*, *dapB*, and *ORF2* (Claims 11, 18, and 22)
- i) DNA encoding SEQ ID NO:2, *asd*, *dapA*, *dapB*, *ddh*, and *ORF2* (Claims 12 and 19)

Art Unit: 1652

- j) DNA encoding SEQ ID NO:2, *asd*, *dapA*, *dapB*, *ddh*, *lysA*, and *ORF2* (Claims 13, 20, and 23)
- k) DNA encoding SEQ ID NO:2, *asd*, *dapA*, *dapB*, *ddh*, *lysA*, and *ORF2* (Claims 14, 21, and 24)
- l) DNA encoding SEQ ID NO:2 and a promoter related to SEQ ID NO:17 (Claims 61-67)

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently in Group II, claims drawn to comprising language with the only requirement being SEQ ID NO:1 are generic; these claims are Claims 2-7 and 15.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the



Art Unit: 1652

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

### *Election*

6. A telephone call was made to Suzanne Ziska on March 11, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

### *Conclusion*


7. A complete response to the instant Office action must contain an election of invention to be examined. If Applicants elect Group II, an election of species is also required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
PONNATHUPURACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1652

KMK

March 12, 2002